From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

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13. Sep. 2006
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Date of mailing *(day/month/year)*	
08 September 2006 (08.09.2006)	
Applicant's or agent's file reference	IMPORTANT NOTICE
P21151WO	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/050209	26 February 2004 (26.02.2004)	

Applicant

CANDOR BIOSCIENCE GMBH et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference P21151WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/EP2004/050209	International filing date *(day/month/year)* 26 February 2004 (26.02.2004)	Priority date *(day/month/year)*
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant CANDOR BIOSCIENCE GMBH		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 30 August 2006 (30.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Ellen Moyse e-mail: pt05@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

CORRECTED VERSION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/EP2004/050209	International filing date *(day/month/year)* 26.02.2004
Priority date *(day/month/year)*	
International Patent Classification (IPC) or both national classification and IPC G01N33/543	
Applicant SANOCHEMIA DIAGNOSTICS DEUTSCHLAND GMBH	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2004/050209

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2004/050209

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-27
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-27
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents are referred to in this communication:

D1 : US 5 616 460 A (FIGARD STEVE D) 1 April 1997 (1997-04-01)
D2 : US 4 931 385 A (BLOCK ELLIOTT ET AL) 5 June 1990 (1990-06-05)
D3 : DE 41 04 128 A (INST MOLEKULARBIOLOGIE AK) 12 March 1992 (1992-03-12)
D4: GB-A-2 062 224 (ORION YHTYMAE OY) 20 May 1981 (1981-05-20)
D5: EZAN E ET AL: "Triton X-100 eliminates plasma proteins interference in a radioimmunoassay for luteinizing hormone-releasing hormone (LHRH) and LHRH analogues." JOURNAL OF IMMUNOLOGICAL METHODS. 1 SEP 1989, vol. 122, no. 2, 1 September 1989 (1989-09-01), pages 291-296, XP002300350 ISSN: 0022-1759
D6: HOLOWNIA P ET AL: "Effect of poly(ethylene glycol), tetramethylammonium hydroxide, and other surfactants on enhancing performance in a latex particle immunoassay of C-reactive protein." ANALYTICAL CHEMISTRY. 15 JUL 2001, vol. 73, no. 14, 15 July 2001 (2001-07-15), pages 3426-3431, XP002300351 ISSN: 0003-2700

2. Novelty

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-27 is not new in the sense of Article 33(2) PCT.

2.2 Document D1 discloses (the references in parenthesis applying to this document): An aqueous buffer to stabilize hepatitis C virus antigen for immunoassay comprising a buffer (MES, HEPES, PIPES), compound A (5 % ethylene glycol and sucrose), a non-ionic detergent (0.01 % Triton X-100), and NaCl (see D1: column 3, line 15 - column 6, line 39; claims 1-10 and 12-19; example 1). The function of the non-ionic detergent is to reduce non-specific binding of antibodies other than the analyte. A kit with the buffer in a vessel and microparticles coated with the antigen is also disclosed.

As can be seen from the above, document D1 discloses in combination all the features defined in claims 1, 5-12, 15-20, and 22-27. Hence the subject-matter of these claim is not new (Article 33(2) PCT).

2.3 Document D2 discloses (the references in parenthesis applying to this document): a blocking solution for an immunoassay comprising a buffer (HEPES), compound A (2% polyethylene glycol and 12% trehalose) and non-ionic detergent (0.3% octylphenoxypoly(ethylene oxy) ethanol) (see D2: examples 3, 4 and 6; claims 6 and 7). The solution and antibody are lyophilized to obtain a concentrate. An assay kit with a vial containing the lyophilized solution (which is reconstituted to a solution with urine), and a dipstick coated with an antibody is also disclosed. The solution does not contain dithiothreitol.

As can be seen from the above, document D2 discloses in combination all the features defined in claims 1, 7-12, 14-25 and 27. Hence the subject-matter of these claim is not new (Article 33(2) PCT).

2.4 Document D3 discloses (the references in parenthesis applying to this document): a stabilizing buffer for the coating of a solid phase with anti-glycogen phosphorylase isoenzyme BB. The buffer solution contains phosphate buffered saline with a pH of 7.3, 2-7% of compound A (sucrose), 0.02-0.1% of non-ionic detergent (Tween 20) and 0.3-0.8% of blocking protein (albumin) (see column 2, lines 1-52; column 3, lines 1-11 and 37-40; column 5, lines 14-27; example 2; claims 1 and 2).

As can be seen from the above, document D3 discloses in combination all the features defined in claims 1-20 and 25. Hence the subject-matter of these claims is not new (Article 33(2) PCT).

2.5 Document D4 discloses (the references in parenthesis applying to this document): a solution for the determination of C-reactive protein comprising a phosphate buffer, compound A (3% polyethylene glycol), a non-ionic detergent (0.1% Tween 20), and NaCl (see D4: page 1, lines 46-81; example 3). Serum samples and antibodies against the analyte are diluted in this buffer. A kit with the antibody fixed to the surface of a plastic tube and a vessel containing the buffer is also disclosed.

As can be seen from the above, document D4 discloses in combination all the features defined in claims 1, 5-12, 14-20, 22, 23-25 and 27. Hence the subject-matter of these claims is not new (Article 33(2) PCT).

3. Inventive step

3.1 Dependent claims 2-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-D6 and the corresponding passages cited in the search report.

4. Clarity

4.1 Claim 2 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The following functional statement does not enable the skilled person to determine which technical feature is necessary to perform the stated function: "an amount effective to immunologically block non-specific antibody binding".
This feature can be defined more precisely by the concentrations given on page 6, lines 4-6 of the description.

4.2 Claims 16-20 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempts to define the subject-matter in terms of the result to be achieved, namely solutions "having the capability of reducing unspecific binding, cross-reactivity and disturbing effects of the matrices" (claim 16), "having the capability of preventing the low-affinity binding (...)" (claims 17-19), and "having the capability to increase the binding activity of antibodies" (claim 20), which merely amounts to a statement of the underlying problems, without providing the technical features necessary for achieving these results.